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June 28, 2024

By Electronic Mail

The Honorable Gerald J. Pappert
11614 U.S. Courthouse
601 Market Street
Philadelphia, PA 19106

Re: *United States of America v. AmerisourceBergen Corp. et al.* (No. 22-cv-5209-GJP)

Dear Judge Pappert:

We represent the Defendants in the above-captioned matter. Defendants write to request the Court's assistance with a discovery dispute. Pursuant to Your Honor's Policies & Procedures, Defendants contacted Chambers to request a conference and were directed to submit a letter. Defendants understand the Government will submit a responsive letter no later than July 12. Thereafter, Defendants are available to appear for a discovery conference or alternatively to file a motion to compel.

I. Overview of the Dispute

This dispute concerns the Government's refusal to produce responsive documents in the possession of the DEA. The parties held several meet-and-confer conferences and exchanged multiple letters over a period of five months in an effort to resolve this dispute. Defendants summarized the relevant discovery requests in a January 11, 2024 letter. (Ex. A.) The topics of these requests include: DEA's interpretation and understanding of the Suspicious Order Monitoring and Reporting obligations; DEA's knowledge of Defendants' Suspicious Order Monitoring systems; DEA's receipt, handling, investigation, and use of Suspicious Order Reports; and Investigations of DEA by other government bodies. *See* Ex. A at 2-5.

The Government agreed only to produce different and narrower categories of the requested documents, it summarized as (1) "Internal DEA communications relating to external communications;" (2) "Internal DEA communications concerning Defendants and the facts in this case;" and, tentatively and subject to further discussion, (3) "Internal DEA communications by DEA personnel who advised Defendants regarding the meaning of the suspicious order reporting laws." Each category, as created and defined by the Government, is subject to further clarification and caveats, as set forth in the Government's May 17, 2024 letter. (Ex. B at 1-3.) The Government otherwise has objected to production of DEA documents on the grounds that it believes such documents are irrelevant and "largely" privileged. *See* Ex. B at 1.

Defendants do not agree to the Government's limits to discovery on these critical and highly-relevant documents. As set forth below, the Government's proposal is based on its own subjective view of relevance and unsubstantiated, categorical privilege assertions. The Government's proposed limitations

The Honorable Gerald J. Pappert
Page 2

ReedSmith

certainly would result in documents key to the defense being improperly withheld and is a black box that provides no meaningful mechanism for Defendants or the Court to understand what documents are being withheld—let alone challenge those decisions. And the proposal does not comport with the Federal Rules’ requirement that discovery be proportional to the needs of the case—most notably here, the Government’s demand for billions of dollars in civil penalties. Defendants accordingly seek the Court’s assistance to resolve this issue.

II. Overview of Defendants’ Position

A. Internal DEA Documents Are Highly Relevant

Internal DEA documents are highly relevant to the Government’s claims and Defendants’ defenses and affirmative defenses. Indeed, the Court already has recognized the potential relevance of this discovery during the most recent status conference. *See* Jan. 22, 2024 Transcript at 21:3-28:2 Yet, the Government is refusing to produce internal communications between DEA personnel relating to the suspicious order monitoring and reporting obligations, including but not limited to what constitutes a “suspicious order,” what it means to “dispel the suspicion,” whether and how the regulatory obligations apply to “orders of interest,” DEA’s interpretation and application (or lack thereof) of the *Masters* decision, and DEA’s efforts to clarify the suspicious order regulations that have been ongoing for almost a decade but are still not enacted. These are documents that go to the heart of the case, but the Government’s position is that this discovery is not relevant to the proper interpretation of the suspicious order reporting requirement or whether Defendants acted reasonably in not reporting any particular orders.

Defendants submit that magistrate and district court opinions in *United States v. American Electric Power Service Corp.* (“*AEP*”) are analogous and relevant to the dispute here. *See* No. C2-99-1182, 2001 U.S. Dist. LEXIS 18723 (S.D. Ohio June 19, 2001) (Mag. J.), *recon. denied* by 2001 U.S. Dist. LEXIS 18722 (S.D. Ohio Aug. 13, 2001). *AEP* concerned the defendants’ compliance with a Clean Air Act permitting requirement that turned on the distinction between “major modifications” and “routine maintenance.” 2001 U.S. Dist. LEXIS 18723 at *4-5. The magistrate concluded that discovery of internal EPA documents on the permitting requirement was appropriate, relying on Sixth Circuit precedent for the proposition that “contemporaneous expressions of opinion by low-ranking officials [are considered] highly relevant and material evidence of the general understanding of ambiguous regulatory provisions.” *Id.* at *15-20 (citing *Ohio Dep’t of Human Servs. v. U.S. Dep’t of Health & Human Servs.*, 862 F.2d 1228, 1235 (6th Cir. 1988)). The district court agreed. 2001 U.S. Dist. LEXIS 18722, at *7-10.

Several factors supported this discovery in *AEP*. *First*, even though the regulation used “common sense” language (like “routine”), the court recognized that the regulation could still be ambiguous. 2001 U.S. Dist. LEXIS 18723, at *18; 2001 U.S. Dist. LEXIS 18722, at *7-8. And, even if unambiguous, the regulation would need to be interpreted “contextually.” 2001 U.S. Dist. LEXIS 18722, at *8. The court further noted that it appeared the regulation “was worded broadly precisely in order to cover the myriad of situations . . . and that the drafters intended the application to be made either on a case-by-case or industry-segment-by-industry-segment basis.” *Id.* at *9. *Second*, there was “a substantial disagreement in [the] case as to the consistency of the EPA’s interpretation over time.” *Id.* at *10. *Third*, there had been a lack of specific guidance to the defendants on the proper application of the regulation. 2001 U.S. Dist. LEXIS 18723, at *18. *And fourth*, both the magistrate and district court took into consideration the early stages of the litigation, deciding it would be premature to preclude such discovery so early in the case. *Id.*; 2001 U.S. Dist. LEXIS 18722, at *8.

The Honorable Gerald J. Pappert
Page 3

ReedSmith

AEP is directly on point. Here, while the definition of “suspicious order” may use “common” language (such as “unusual size”), it also requires a contextual interpretation. Indeed, DEA itself has emphasized that the “determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the relevant segment of the regulated industry.”¹ Moreover, as in *AEP*, there is a “substantial disagreement in this case as to the consistency of the [DEA’s] interpretation over time.” And this Court already has observed that DEA-related discovery could be relevant to Defendants’ “state of mind or their culpability” and asked how the Court could “draw that line, at this stage” to exclude such issues from the case at the start of discovery. *See* Jan. 22, 2024 Transcript at 26:5-17.

Importantly, this discovery also is relevant to *many other issues and defenses*, including: the nature and inconsistency of DEA’s guidance over the years; DEA’s awareness of Defendants’ and other registrants’ programs; and conflicts between the Government’s litigation posture and prior DEA positions. This is not a fishing expedition. Defendants know relevant and responsive documents exist because DEA previously produced a limited number of such documents as a non-party in the federal opioid MDL. DEA-produced documents, and other documents that summarize interactions with DEA, demonstrate that:

- (1) DEA was aware of, allowed, and even endorsed the ambiguity and lack of guidance surrounding the suspicious order reporting requirement;
- (2) DEA knew and accepted that distributors used suspicious order monitoring programs that differentiated between “orders of interest” and “suspicious orders” and did not automatically report all orders of interest; and
- (3) DEA has taken positions in the past that directly conflict with the positions the Government is taking here, including whether distributors should limit their reporting to “truly suspicious” orders.

Defendants are entitled to explore DEA-related issues in detail, with the benefit of full party discovery. The Government must search for and produce documents responsive to Defendants’ discovery requests.

B. The Government Cannot Refuse to Produce Documents Based on Its Unilateral, Subjective Assessment of Relevance

The Government may not refuse to respond to discovery requests based on its own assessment of relevance. “It is not for a party to determine, by a unilateral review of documentation, whether information is relevant to the case.” *Sanchez v. U.S. Airways, Inc.*, 202 F.R.D. 131, 135 (E.D. Pa. 2001). Instead, “[a]t the discovery stage of the litigation, the evidence sought need only be relevant, and ‘need not be admissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.’” *Id.* (quoting Fed. R. Civ. P. 26(b)(1)).

Importantly, this basic tenet applies equally to the Government as the plaintiff. “When the United States is a party to litigation, it is ‘subject to the rules of discovery’ as is any other litigant.” *Herrmann v. United States*, 127 Fed. Cl. 22, 34 (2016); *see also United States v. Procter & Gamble Co.*, 356 U.S. 677, 681

¹ While this Court previously rejected Defendants’ argument at the motion to dismiss stage that the statute is unconstitutionally vague, that does not mean that the statute necessarily is unambiguous. A statute or regulation can be ambiguous, such that a court could benefit from additional context in interpreting the relevant language, without reaching the level of unconstitutional vagueness.

The Honorable Gerald J. Pappert
Page 4

ReedSmith

(1958) (“The Government as a litigant is, of course, subject to the rules of discovery.”). “This means that the government, as a litigant, cannot use its executive power to ‘dictate what evidence is admissible in a court of law, or whose testimony the court may hear.’” *Herrmann*, 127 Fed. Cl. at 34; *see also Gulf Grp. Gen. Enters. Co. v. United States*, 98 Fed. Cl. 639, 646 (2011) (“When the United States is a party to litigation, ‘judicial control over the evidence in a case cannot be abdicated to the caprice of executive officers.’” (quoting *United States v. Reynolds*, 345 U.S. 1, 9-10 (1953))).

This tenet is especially true in light of the importance of the issues at stake and the billions of dollars in civil penalties the Government seeks. *See* Fed. R. Civ. P. 26(b)(1) (providing for discovery that is “proportional to the needs of the case,” including consideration of “the importance of the issues at stake in the action [and] the amount in controversy”); *see also, e.g., P.H. Glatfelter Co. v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 19-CV-2215, 2021 U.S. Dist. LEXIS 145549, *11 (M.D. Pa. Aug. 4, 2021) (allowing discovery in light of the “enormous amount in controversy” of nearly \$60 million); No. 18-cv-11273, *Occidental Chem. Corp. v. 21st Century Fox Am., Inc.*, 2022 U.S. Dist. LEXIS 246234, *155 (D.N.J. Jan. 11, 2022) (allowing broad discovery based in part on the damages demand of hundreds of millions of dollars).

C. The Government Cannot Make Categorical Privilege Assertions

Defendants also object to the Government’s categorical assertion of the attorney-client and deliberative process privilege. Despite acknowledging in its May 17 letter that “privilege assertions cannot be made on a categorical basis,” the Government nevertheless insists that it will not produce categories of documents that it “believe[s]” are “largely” privileged. Ex. B at 5. The Government is correct that its categorical privilege assertion is improper and not permitted. *See, e.g., United States v. Rockwell Int’l*, 897 F.2d 1255, 1265 (3d Cir. 1990) (“[C]laims of attorney-client privilege must be asserted document by document, rather than as a single, blanket assertion.”); *Doe v. Schuylkill Cnty. Courthouse*, 343 F.R.D. 289, 295 (M.D. Pa. 2023) (“[W]hen addressing legal questions regarding whether the attorney client privilege applies to particular documents, we are cautioned to eschew any categorical approach which cloaks or rejects the privilege in a wholesale fashion without regard to the specific content of particular documents.”).²

The Government’s assertion of deliberative process privilege fares even worse, as the Government has taken *none* of the steps the law requires to assert such a privilege. The initial burden of establishing whether the deliberative process privilege applies is on the government. *Redland Soccer Club v. Dep’t of the Army*, 55 F.3d 827, 854 (3d Cir. 1995); *Del. Riverkeeper Network v. Del. River Basin Comm’n*, 300 F.R.D. 207, 211 (D.N.J. 2014). Courts impose three procedural requirements on the assertion:

- (1) the head of the department which has control over the matter must make a formal claim of privilege after actually considering the matter;
- (2) the responsible agency official must provide precise and certain reasons for asserting the privilege over the government information or documents at issue; and
- (3) the government information or documents sought to be shielded from disclosure must be identified and described.

² The only case the Government cited in support of its position in its May 17 letter involved a discovery request seeking “all communications” between a party and its outside law firm. *See City of Chicago v. DoorDash, Inc.*, 2023 U.S. Dist. LEXIS 91698, *7-8 (N.D. Ill. May 25, 2023). This case is distinguishable on its face.

The Honorable Gerald J. Pappert
Page 5

ReedSmith

Del. Riverkeeper, 300 F.R.D. at 211; see also, e.g., *Three Bros. Supermarket, Inc. v. United States*, 2020 U.S. Dist. LEXIS 159660, *4-5 (E.D. Pa. Sept. 1, 2020). “This process ensures that a claim of privilege is not casually invoked.” *Three Bros.*, 2020 U.S. Dist. LEXIS 159660, at *5 (citing *United States v. O’Neil*, 619 F.2d 222, 225 (3d Cir. 1980)). Moreover, “[t]he privilege, once determined to be applicable, is not absolute.” *Redland Soccer Club*, 55 F.3d at 854. “[T]he district court should balance the competing interests of the parties” and, if the party seeking discovery can show that “its need for the documents outweighs the government’s interest,” then the privilege must yield. *Id.* (citations omitted).

Here, the Government has not complied with *any* of these requirements. Requiring the Government to comply with these basic and well-established rules is not burdensome, unfair, or unusual. The Government may assert either privilege subject to that privilege’s requirements, described with the requisite detail on a document-by-document privilege log. Such assertions can then be challenged if appropriate, with *in camera* review if necessary, as is common in civil litigation.

III. Defendants’ Requested Relief

The Government’s agreement to produce only certain self-determined subsets of internal DEA documents is not sufficient. *First*, it is inconsistent with the rules of discovery to the extent it gives the Government the power to decide what is relevant. *Second*, it is vague and subjective. *Third*, it would allow for production of only certain documents on particular topics, which easily could paint an incomplete and misleading picture for the parties, the Court, and the jury on important issues. *Fourth*, it is a black box. It provides no clarity to Defendants or the Court as to what is not being reviewed or produced and would provide Defendants with no meaningful ability to challenge any of the Government’s decisions.

Accordingly, Defendants respectfully request that the Court compel the Government to comply with its discovery obligations and produce internal DEA documents responsive to Defendants’ requests, subject only to any proper assertion of the attorney-client or deliberative process privilege, consistent with the requirements under the law for those privileges, including production of a privilege log.

Respectfully submitted,

/s/ Robert A. Nicholas

cc: All counsel of record (*via email*)

EXHIBIT A



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January 11, 2024

By Electronic Mail

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District of New Jersey
970 Broad Street, 7th Floor
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**Re: *United States of America v. AmerisourceBergen Corporation et al.*
(E.D. Pa. Civ. A. No. 22-5209-GJP)**

Dear Jordann:

I write regarding the United States' Objections and Responses to Defendant AmerisourceBergen Corporation's First Set of Interrogatories and Defendants' First Set of Requests for Production of Documents. As summarized below, the Government's responses contain significant and pervasive deficiencies. Among other things, the Government: (i) fails to identify and provide the factual basis for each claimed violation despite quantifying the number of alleged violations in the Complaint and its discovery responses; (ii) refuses to produce internal DEA documents bearing on key issues, including the meaning and application of the suspicious order reporting obligations, the DEA's knowledge of Defendants' suspicious order monitoring systems, and the DEA's practices with respect to the receipt, investigation, and use of suspicious order reports; (iii) relies upon improper blanket privilege assertions; (iv) cherry-picks just twenty customer files for production, while withholding tens of thousands of additional, relevant customer files; (v) imposes an arbitrary date cut-off for responsive documents; and (vi) restricts its responses to limited categories of DEA employees and refuses to search for responsive documents in the hands of other relevant governmental entities.

We summarize below the major categories of deficiencies in the Government's responses and request that the Government promptly remedy them. We are available to meet and confer on January 17th to discuss these issues and hope to avoid the need to raise them with the Court.

A. Ongoing Failure To Disclose the Alleged Violations

Interrogatory No. 1: This interrogatory asks the Government to identify all Alleged Violations,¹ describe the factual basis for each Alleged Violation, and identify individuals (other than Defendants' representatives) with knowledge of each Alleged Violation. The Government objects that "this

¹ Capitalized terms not otherwise defined in this letter have the meanings ascribed to them in the Interrogatories and RFPs.

Jordann Conaboy, Esq.
Page 2

ReedSmith

Interrogatory should be deferred to a later time,” and responds that it will produce preliminary lists for limited categories of Alleged Violations “in the ordinary course of discovery, once a protective order is entered.” This interrogatory goes to the heart of the case and the Government cannot withhold this critical information any longer.

Importantly, the Government filed this action with the benefit of a massive investigative record. The Complaint alleges that Defendants committed “at least hundreds of thousands” of Alleged Violations, Compl. ¶¶ 443, 446, but, other than a few examples, fails to identify them. The Government’s discovery responses have now increased the number of Alleged Violations to “more than a million.” *See* Interrog. R&O, Gen. Stmt. ¶ 10. The information requested is vital, and Defendants need to know which specific orders are in play and why the Government believes a violation occurred so they can gather the relevant facts and prepare their defenses. Even if the Government cannot identify every Alleged Violation at this time, it must answer based on its current knowledge, and then supplement its response if it later identifies additional Alleged Violations. *See, e.g., United States ex rel. Dougherty v. Guild Mortg. Co.*, 2020 WL 3542391, *3-*5 (S.D. Cal. Jun. 30, 2020) (ordering government to identify alleged false claims, and noting that its “two-year statutory investigation should have enabled it to identify the specific allegations of wrongdoing as soon as discovery commenced”); *Oklahoma ex rel. Edmondson v. Tyson Foods, Inc.*, 2007 WL 649332, at *5 (N.D. Okla. Feb. 26, 2007) (ordering plaintiff to identify claimed environmental violations based on available information).

B. Refusal To Produce Internal Documents Reflecting the DEA’s Interpretation and Understanding of the Suspicious Order Monitoring and Reporting Obligations

RFP Nos. 1-14, 48, 67: These requests seek documents regarding the meaning and application of the Suspicious Order Monitoring and Reporting Obligations at the heart of the lawsuit. The Government has objected to producing responsive internal DEA documents and communications on the basis that “non-public or informal understandings of agency officials . . . concerning the meaning of a regulation are not relevant.” *See* RFP R&O, Comm. Obj. ¶ 7. Instead, the Government has agreed to produce only external communications (RFP Nos. 1(b), 1(c), 3, 4, 5, 7, 8, 9, 67) or documents previously produced by the DEA in the Opioid MDL (RFP Nos. 6, 9). And for the remaining requests, the Government has refused to produce anything (RFP Nos. 1(a), 1(d), 1(e), 2, 10, 11, 12, 13, 14, 48).

The Government’s relevance objection is baseless. The DEA’s internal interpretation and understanding of the reporting framework is relevant to numerous issues in the case, including (i) the reasonableness of Defendants’ conduct, (ii) any potential penalty assessments, and (iii) impeachment evidence to challenge testimony by governmental witnesses. For example, Defendants are entitled to defend against the Government’s negligence allegations by showing that their conduct was consistent with the actions, understanding, and guidance of DEA officials overseeing the reporting obligations. They are also entitled to show that there was confusion within the DEA regarding the meaning and application of the reporting requirement, and that the DEA knew of but ignored and perpetuated confusion within the industry.

The prejudice created by the Government’s blanket objection is compounded because the objection sweeps in broad swaths of documents that do not even fit within the purported rationale. For example, the Government has agreed to produce external communications between the DEA and Defendants, other Registrants, or industry groups regarding the Suspicious Order Monitoring and Reporting Obligations, what constitutes a Suspicious Order, and/or how to operate a suspicious order monitoring system, including requests for clarification or guidance and any DEA responses. Yet, it arbitrarily and improperly objects to producing internal documents reflecting the very same communications. If a DEA official took

Jordann Conaboy, Esq.
Page 3

ReedSmith

notes during a call with Defendants or wrote an internal memo or email about a responsive communication, for example, those documents are no less relevant and must be produced. Internal documents discussing communications with Defendants or industry groups, including whether or how to respond, are discoverable because they may show, for instance, that DEA officials agreed with Defendants' actions and/or interpretations, intentionally withheld guidance, or were unsure themselves how to apply the standards.

The Government further objects to producing internal documents on executive privilege grounds. However, the law is clear that the Government cannot assert boilerplate privilege objections to withhold documents on a blanket basis. The Third Circuit has instructed that "the deliberative process privilege, like other executive privileges, should be narrowly construed." *Redland Soccer Club, Inc. v. Dep't of Army of U.S.*, 55 F.3d 827, 856 (3d Cir. 1995). To invoke the privilege, the Government must identify and describe the specific documents being withheld and provide "precise and certain reasons for preserving the confidentiality of the governmental communications." *Three Bros. Supermarket Inc. v. United States*, 2020 WL 5231575, at *2 (E.D. Pa. Sept. 1, 2020). Likewise, the law enforcement privilege must be raised on a targeted basis in accordance with strict procedures. *See United States v. Wey*, 252 F. Supp. 3d 237, 250 (S.D.N.Y. 2017). Based on our prior experience in the Opioid MDL, we have significant concerns about the DEA's overreliance and unsupported use of executive privilege. Even if the Government could assert a viable claim of privilege over any particular document (something it has not attempted to do), executive privileges are not absolute. Here, particularly given that the Government is accusing Defendants of pervasive violations of a vague and subjective reporting obligation and seeking to penalize them billions of dollars, it is inappropriate for the Government to invoke a blanket assertion of executive privileges to deprive Defendants of information essential to their defenses.

Interrogatory No. 2 and RFP No. 93: Interrogatory No. 2 and RFP No. 93 ask the Government to provide information and documents about the meaning of the phrase "dispel[] all suspicion" as used throughout the Complaint. The Government has referred Defendants to a list of purported legal authorities and its opposition to Defendants' Motion to Dismiss and objected to producing any documents. The Government's responses are evasive and inadequate. The Government has made "dispelling suspicion" a centerpiece of its case. *See, e.g.*, Compl. ¶¶ 4, 10, 53-56, 208-211, 218, 239, 248, 256, 263, 276, 443-485; *see also* MTD Op. (repeatedly referencing the standard that Defendants must "dispel suspicion"). Among other things, the Government has alleged that (i) "upon discovering an order with one or more indicia of suspicion, a distributor must 'report the order to DEA, unless the distributor investigates the order and dispels all suspicion relating to the order'" (Compl. ¶ 54); a distributor must conduct "an adequate investigation" (*id.* ¶ 55); (iii) Defendants' reviewers "typically" did not take any "real suspicion-dispelling steps" (*id.* ¶ 248); and (iv) Defendants committed "at least hundreds of thousands" of violations by not adequately dispelling suspicion for shipped orders (*id.* ¶ 443). The Government is well aware that the regulation says nothing about "dispelling the suspicion," so the Defendants are entitled to understand what the Government understood such a requirement to mean regardless of whether or not those communications happened internally at the DEA or between DEA and third parties.

C. Selective and Incomplete Production of Documents Regarding the DEA's Knowledge of Defendants' Suspicious Order Monitoring Systems

RFP Nos. 57-63, 65, 66, 68-72, 92, 95: These requests seek documents regarding the Government's knowledge of Defendants' diversion control programs and suspicious order monitoring systems ("SOMS"). These documents undeniably are relevant to rebutting the Government's allegations that

Jordann Conaboy, Esq.
Page 4

ReedSmith

Defendants had deficient systems. *See* Compl. ¶¶ 96-270 (175-paragraph section titled “Defendants’ CSA Compliance Programs Suffered from Serious Systemic Defects that Enabled Significant CSA Violations”). To defend against these allegations, Defendants are entitled to show that the DEA, at all relevant times, knew how Defendants’ systems were designed and worked—including from its audits of Defendants’ distribution centers—but never took any adverse action related to Defendants’ diversion control programs. Instead, the DEA renewed the registrations for each of Defendants’ distribution centers on an annual basis, something the DEA by law could do only if it determined that registration was in the “public interest,” including that Defendants maintained “effective controls against diversion.” 21 U.S.C. § 823. Defendants have the right to discovery to develop their defenses that the Government’s allegations of pervasive defects in Defendants’ systems are directly contradicted by the Government’s own prior conduct and are entirely inconsistent with its actions, a matter that the Court made clear during oral argument on the Motion to Dismiss is one to be explored during discovery and in testimony at trial.

The Government’s attempt to selectively produce only certain relevant documents is improper. The Government cannot unilaterally limit its discovery obligations to searching only external communications, *see* Resp. to RFP Nos. 58-60, 71-72, or limit its production to documents it “relied” on for particular allegations rather than all documents “regarding” those allegations, *see* RFP Nos. 92, 95. The Government has initiated this large action against Defendants after a ten-year investigation, and it cannot now create an incomplete and misleading record by selectively producing documents.

D. Refusal To Produce Documents Regarding the DEA’s Receipt, Handling, Investigation, and Use of Suspicious Order Reports

RFP Nos. 27-29, 31-39, 64: These requests seek documents regarding DEA’s handling of Suspicious Order Reports. The Government has refused to search for or produce these documents, with two limited exceptions. *See* Resp. to RFP No. 28 (agreeing to “search the DEA’s database of suspicious order reports and produce suspicious order reports received from Defendants”); Resp. to RFP No. 31 (agreeing to produce documents sufficient to show the annual number of Suspicious Order Reports DEA received for the period 2014 to 2022 in total and from Cardinal and McKesson).

The Government cannot block discovery into the DEA’s use of—or failure to use—Suspicious Order Reports. In its own Complaint, the Government has specifically alleged that suspicious order reporting is intended “to provide DEA investigators in the field with information regarding potential illegal activity in an expeditious manner,” and that Defendants’ alleged failures to report “enabl[ed] diversion” and “fueled the opioid crisis.” Compl. ¶¶ 1, 57; *see also id.* ¶¶ 1, 12. Defendants are now entitled to disprove the allegations against them, including the causal link the Government attempts to draw, by showing that the DEA did not act on Suspicious Order Reports. The Court has already recognized that the DEA’s desire for fewer reports, and lack of use of reports that the DEA did receive, would be particularly notable for cross-examination of Government witnesses. *See* Sept. 9, 2023 Hearing Tr. at 204:4-8. Indeed, the Office of Inspector General has sharply criticized DEA’s practice of handling Suspicious Order Reports and noting that DEA was unable to locate Suspicious Order Reports during the course of its investigation of DEA’s actions in addressing the opioid crisis. Moreover, the Government concedes that “the factors pertinent to assessing a civil penalty” are proper subjects of discovery. *See* RFP R&O, Comm. Obj. ¶ 2. One such factor is the public harm that resulted from a defendant’s violations. Defendants have the right to show that the DEA failed to use Suspicious Order Reports and thus no harm, in fact, resulted from Defendants’ alleged failure to report suspicious orders that never would have been used by DEA. For

Jordann Conaboy, Esq.
Page 5

ReedSmith

similar reasons, information about the DEA's use or non-use of the daily controlled substances sales reports ABDC submitted to the DEA is relevant. *See* RFP No. 64.

Information about estimated and actual numbers of Suspicious Order Reports is another proper area for discovery. In connection with the 2020 SOR Notice, the DEA provided estimates of the number of Orders Received Under Suspicious Circumstances ("ORUSC") and Suspicious Order Reports it expected on an annual basis across the entire industry. In particular, the DEA estimated 339,000 ORUSC and approximately 67,000 Suspicious Orders for the entire industry. But, here, the Government inconsistently contends that Defendants alone had *millions* of ORUSC and should have reported more than 100,000 Suspicious Orders each year. Defendants are entitled to understand how those DEA estimates (and any others) were compiled and the reasons for the massive discrepancy between those estimates and the allegations against Defendants. Similarly, the Government has suggested that Defendants underreported suspicious orders in comparison to two competitors. Compl. ¶ 252. By making such comparisons, the Government has opened the door to discovery of the relative numbers of suspicious orders reported across the industry, lest it paint a potentially unfair and inaccurate picture of what has occurred. Finally, documents going to actual or potential over-reporting of Suspicious Orders, and any resulting impact on patient care, are plainly relevant to rebutting and contextualizing the number of Alleged Violations and comparisons to other distributors, as well as assessing the reasonableness of Defendants' conduct and interpretation of the reporting obligations.

E. Refusal to Produce Documents Regarding Investigations of the DEA

RFP Nos. 74-77: These requests seek documents regarding government investigations criticizing the DEA and calling for additional guidance to help distributors comply with the Suspicious Order Monitoring and Reporting Obligations. The Government has no basis to withhold these key documents or limit its search for relevant documents to the DEA if the Government reasonably believes other Government departments, offices or agencies possess relevant information. Like the internal DEA documents discussed above, they go to the meaning and application of the reporting obligations at the heart of the case and are accordingly relevant to the reasonableness of Defendants' conduct, potential penalty assessments, and impeachment evidence to challenge testimony by governmental witnesses. Defendants are entitled to show that the Government is seeking to penalize them billions of dollars for not reporting more orders during the same period the DEA was failing to heed calls for clarifying guidance. Defendants are also entitled to show that the DEA did not regularly use Suspicious Order Reports which, again, goes to the issue of public harm. Finally, for the reasons explained above, the Government's boilerplate privilege objections cannot justify withholding documents on a blanket basis.

F. Cherry-Picking Information and Documents Regarding Alleged Violations and Applicable Customers

RFP Nos. 16-26, 30, 42-45, 51-54: These requests seek documents regarding the Alleged Violations (RFP No. 16) and the Applicable Customers, including analysis received, performed, or reviewed by the DEA (RFP Nos. 17, 18); communications with state agencies (RFP No. 19); communications with Defendants regarding Suspicious Order Reports and related communications between DEA headquarters and DEA field offices (RFP Nos. 20, 30); Suspicious Order Reports from sources other than Defendants (RFP No. 43); data on the number of Suspicious Order Reports for each Applicable Customer (RFP No. 42); actions against Applicable Customers (or related individuals) in response to Suspicious Order Reports, or to revoke their registrations (RFP Nos. 26, 52, 53); documents obtained from third parties

Jordann Conaboy, Esq.
Page 6

ReedSmith

regarding the Alleged Violations (RFP No. 21); investigative files related to potential diversion including estimates of diversion (RFP Nos. 22, 24); audit reports, registration files, ARCOS data, and registration status for Applicable Customers (RFP Nos. 23, 25, 51, 54); and DEA notice of, and action in response to, distributor terminations of Applicable Customers (RFP Nos. 44, 45).

These requests go to the core of the case—the Alleged Violations and the customers who placed the orders at issue. The Court has already ruled that Defendants must have the “opportunity during discovery to develop the record regarding each individual alleged violation.” MTD Op. at 39 n. 12. Nevertheless, the Government objects on undue burden grounds to collecting, reviewing, and producing investigative and audit files from its “IMPACT” system for all Applicable Customers because the “Applicable Customers include more than 20,000 DEA registrants and there are more than a million Alleged Violations.” *See* RFP R&O, Comm. Obj. ¶ 5. It further objects that the “DEA cannot reasonably preserve, let alone collect, review, and produce, comprehensive custodial documents pertaining to each of the more than 20,000 . . . Applicable Customers or the more than a million Alleged Violations.” *Id.* Instead, it agrees to produce IMPACT files and custodial documents for just twenty customers. *See id.*; Interrog. R&O, No. 11.

The Government’s pursuit of expansive liability based on an extremely small, cherry-picked group of customers is a clear violation of its discovery obligations. Having chosen to file a lawsuit putting more than a million orders from more than 20,000 customers at issue and to demand a separate penalty for each Alleged Violation, the Government cannot selectively produce documents for just twenty customers it believes are helpful to its case while barring all discovery for the remaining 99.9% of customers.

Moreover, the Government’s undue burden and proportionality objections fail on many levels. First, the scope of discovery that the Government must reasonably provide is necessarily greater where, as here, it has filed an affirmative claim for relief in the billions of dollars. *See, e.g., United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, 2018 WL 8459926, at *11 (C.D. Cal. Dec. 14, 2018). Second, the Government itself imposed enormous burdens on Defendants during its ten-year investigation, serving more than 40 subpoenas totaling more than 450 requests, and it continues to make expansive demands in this litigation. For example, while the Government refuses to produce IMPACT or custodial files for all but twenty customers, it has broadly demanded—and continues to demand—that Defendants produce documents for *all* customers, not just the Applicable Customers. “Discovery is never a one-way street, the outcome of which must favor one or the other of the litigants.” *Velez v. City of Chicago*, 2021 WL 3231726, *3 (N.D. Ill. July 29, 2021), and especially so when billions of dollars are at stake and the Government is accusing Defendants of “fueling” the opioid crisis.

The Government further objects that the DEA’s customer files are irrelevant to the extent they contain information in the possession of the DEA, but unknown to Defendants. That is plainly wrong. Such information bears on the reasonableness of Defendants’ conduct. For example, if the DEA knew similar facts about a customer as Defendants but took no action, the DEA’s conduct would bear on the reasonableness of Defendants’ conduct, whether Defendants knew about it or not. DEA files are also relevant to the issue of public harm. As discussed above, the Government has alleged that Defendants’ alleged failure to report Suspicious Orders “enable[d] diversion of controlled substances, which fueled the country’s opioid epidemic” (Compl. ¶ 11), and it has cherry-picked a handful of customers to advance that narrative. Defendants are not only entitled to put the Government to its proof and contest these allegations, but they are also entitled to highlight customers as to whom the DEA failed to act on Suspicious Order Reports or alternatively cleared of any wrongdoing. In short, the Government cannot

Jordann Conaboy, Esq.
Page 7

ReedSmith

insist on telling a story for its chosen customers, and deny Defendants the opportunity to counter with full stories about these or other Applicable Customers.

We are willing to meet and confer regarding the reasonable scope of customer discovery. Indeed, now that the Court has dismissed claims for penalties for Alleged Violations occurring before October 24, 2018, some of the customers identified in the Complaint are no longer relevant, and we would expect that the overall number of Applicable Customers has decreased. However, to facilitate those discussions, the Government must first identify the Alleged Violations so that we know what customers are at issue, how many Alleged Violations the Government is claiming for each customer, and when the Alleged Violations occurred.

Finally, given the Government's statement on preservation in Common Objection No. 5, we are concerned that it may not have taken adequate steps to preserve relevant evidence. We would like to discuss the timing of the Government's preservation efforts and the steps it took during our meet and confer.

Interrogatory Nos. 9 and 10: In paragraph 165 of the Complaint, the Government alleged that "ABDC regularly shipped orders to customers . . . CSRA knew were likely facilitating diversion of controlled substances." These interrogatories ask the Government to identify those customers, provide the factual basis for the allegation that CSRA "knew" each customer was "likely facilitating diversion," and provide information about any investigation or other steps the Government took with respect to those customers. The Government's responses focused on ten customers but make clear they are only "example customers." Please advise whether the Government is aware of additional customers that it contends are covered by Paragraph 165, or whether this is a complete list based on the information currently available to the Government.

Interrogatory No. 11: This interrogatory asks the Government to identify every Applicable Customer it contends engaged in diversion of controlled substances. The Government provided a list of twenty customers that it contends "engaged in or facilitated the diversion of controlled substances." Please advise whether the Government is aware of additional customers responsive to this interrogatory, or whether this is a complete list based on the information currently available to the Government. In addition, please be prepared to discuss why the Government drew a distinction between "engaged" and "facilitated" and the significance of that distinction.

Interrogatory No. 12: This interrogatory asks the Government to identify, for Pharmacies 1-9 in the Complaint, the names of current or former DEA officials who were involved in, or have knowledge of, registration approval and/or renewals and investigations into potential diversion. The Government's responses cross-reference its responses to Interrogatory Nos. 3(a) and 3(h). Those responses, however, do not provide the requested information. This information is plainly relevant and should be provided for the pharmacies that are still at issue.

Interrogatory No. 13: This interrogatory asks the Government to identify, for Pharmacies 1-9 in the Complaint, all Suspicious Orders Reports that the DEA received for each customer, the steps the DEA took to investigate each Suspicious Order Report, and how the DEA resolved each Suspicious Order Report. The Government has again objected on relevance grounds. As discussed above, information about the DEA's receipt and investigation of Suspicious Orders Reports is relevant to the reasonableness of Defendants' conduct, as well as the issue of public harm, and the Government has not articulated any argument as to why discovery sought by Defendants should be so limited, particularly in proportion to the massive penalties sought in this action. Accordingly, this information must be produced for the pharmacies that are still at issue.

Jordann Conaboy, Esq.
Page 8

ReedSmith

G. Improper Scope Limitations

The Government has improperly restricted the scope of its responses in two respects. First, it has arbitrarily imposed a hard date cut-off. Second, it has limited its search for responsive documents to an incomplete universe of certain DEA files and refused to search other governmental entities.

Relevant Time Period. With regard to timing, other than agreeing to produce the minimal documents contained within the DEA's Opioid MDL production or a handful of IMPACT files, the Government has refused to search for or produce any documents before January 1, 2014. This inflexible date cut-off makes no sense. First, the Government asked for and obtained massive quantities of documents pre-dating January 1, 2014 in its ten-year investigation. Moreover, at the Government's request, Defendants provided access to their productions in the Opioid MDL, which go back even further in time. Second, the Complaint itself references events pre-dating January 1, 2014, such as the 2007 Orlando settlement. Defendants are entitled to take discovery related to these allegations. Third, while the Court has now dismissed the Government's claims for Alleged Violations occurring between January 1, 2014 and October 23, 2018, certain events taking place before or during that period are relevant. For example, the DEA's interactions with Defendants and the industry prior to January 1, 2014 regarding the Suspicious Order Monitoring and Reporting Obligations are plainly relevant and must be produced. The Government's blanket date cut-off is unreasonable and unfair.

Scope. The Government has also imposed unreasonable search restrictions. As a threshold matter, it has improperly limited its search for responsive documents to the DEA. *See* RFP R&O, Gen. Stmt. No. 1. The United States, not the DEA, is the Plaintiff. Under Fed. R. Civ. P. 34, Defendants' requests to the United States extend to responsive documents in the possession, custody, or control of other relevant governmental agencies, entities, or instrumentalities. *See, e.g., North Dakota v. United States*, 2021 WL 6278456, at *6 (D.N.D. Mar. 24, 2021); *Tri-State Hosp. Supply Corp. v. United States*, 226 F.R.D. 118, 126-26 (D.D.C. Feb. 28, 2005). For present purposes, and without waiver of their rights, Defendants narrow their requests to the DEA, DOJ, GAO, OIG, and OMB, all of which possess information relevant to the Government's claims and Defendants' defenses, and demand that the Government search for and produce responsive documents from each of these entities.

Moreover, even as to the DEA, the Government attempts to restrict its production to limited categories of DEA employees. *See* RFP R&O, Gen. Stmt. No. 5. Defendants do not agree to those limitations, which appear to exclude large numbers of potentially relevant custodians both at DEA Headquarters and DEA field offices around the country. *See, e.g.,* RFP No. 40, 41. Defendants will meet and confer with the Government regarding an appropriate list of custodians. To assist in those discussions, Defendants served discovery requests asking the Government to identify relevant witnesses and to produce organizational charts. *See* Interrogatory Nos. 1(d), 3, 12; RFP No. 81. The Government, however, has failed to provide complete or adequate responses to these requests. Instead, it has referred Defendants to its initial disclosures (which do not provide the requested information) and IMPACT files that have not been produced, agreed to produce an organizational chart for only one part of the DEA, and provided the names of only certain section heads. The Government must fully respond to these requests to allow Defendants to engage in meaningful and informed discussions regarding appropriate custodians.

Jordann Conaboy, Esq.
Page 9

ReedSmith

H. Other Deficiencies

In addition to the categories above, the Government must also remedy the following deficiencies:

Interrogatory Nos. 3(f) and 4 and RFP Nos. 82 and 83: These requests seek information and documents regarding the Defendants' Paperwork Reduction Act defense. The Government refused to respond on the ground the issue was raised in Defendants' Motion to Dismiss and because it is unduly burdensome. While the Court's ruling moots the PRA defense for the pre-SUPPORT Act claims, the PRA defense remains viable with respect to the post-SUPPORT Act period. For instance, if the Government seeks to impose liability based solely upon Defendants allegedly failing to maintain documents, when no recordkeeping obligation was ever approved, Defendants would have a PRA defense. Moreover, the Government's undue burden objection cannot justify failure to respond to these requests. There is nothing burdensome about identifying whether the DEA obtained approval from OMB for any collection of information related to the Suspicious Order Monitoring and Reporting Obligations. Either it did or did not.

Interrogatory No. 7 and RFP Nos. 89-91: This interrogatory asks the Government to identify all individuals interviewed by the DEA or DOJ in connection with the AmerisourceBergen Investigation or this lawsuit. The RFPs seek DEA Form 6 Reports of Investigation, summaries, or transcripts for any interviews conducted, and all witness statements obtained, in connection with the AmerisourceBergen Investigation, along with communications with Defendants' current and former employees. The Government's interrogatory answer is incomplete because it is admittedly a "non-exhaustive list," and the Government's RFP responses are deficient because the Government has agreed to search only certain IMPACT files. The Government must produce this targeted set of documents regardless of where it is maintained. Finally, all of the responses are inadequate because the Government purports to limit the start of the AmerisourceBergen Investigation to 2017, even though the investigation began over five years earlier.

Interrogatory No. 8 and RFP No. 94: This interrogatory asks the Government to provide the factual basis for the profitability allegations in paragraphs 80-85 of the Complaint, including the methodology and data it used and all calculations underlying the allegations. RFP No. 94 seeks all documents regarding those calculations. The Government's responses do not provide or produce the requested information or calculations. Because these are calculations that the Government performed, based upon information within its possession, Defendants have no other way of determining precisely what they are or how they were derived. Given the prominence of this information in the Complaint, *see* Compl. ¶¶ 80-86, and the fact that profitability is a penalty factor, these materials should be provided as soon as possible so that the Defendants may respond.

RFP No. 15: This request seeks documents regarding the DEA's estimates of diversion for prescription opioids pursuant to the SUPPORT Act. The Government's refusal to search for responsive documents is improper. These documents are relevant to assess the reasonableness of the Government's allegations that Defendants should have reported more than a million additional Suspicious Orders. Indeed, Defendants may be able to establish the unreasonableness of the Government's allegations by comparing the number of Alleged Violations to the Government's own estimates of diversion.

RFP Nos. 46 and 47: These requests seek documents regarding: (i) the DEA's decision to discontinue its practice of notifying other distributors when it received notice that a distributor had terminated a customer's ability to purchase controlled substances; and (ii) the DEA's consideration of whether and to what extent distributors should be provided with access to ARCOS data showing a customer's purchases

Jordann Conaboy, Esq.
Page 10

ReedSmith

of controlled substances from other distributors. The Government has refused to search for or produce any responsive documents. These documents are relevant to limitations that the DEA imposed on information available to registrants when carrying out their Suspicious Order Monitoring and Reporting Obligations, and thus the reasonableness of Defendants' conduct. The Government has not sufficiently articulated why the burden of collecting and producing such information would not be proportionate to the needs of this case.

RFP Nos. 49, 50, 55, and 56: These requests seek documents regarding the DEA's registration and renewal files for Defendants' distribution centers, the DEA's audits of Defendants' distribution centers, and the applicable DEA manuals, policies, procedures, and guidelines governing the performance of those functions. The Government inappropriately limits its responses to documents contained in the "DEA's centralized repository for registration and renewal files" and IMPACT files, while categorically excluding documents, such as emails, located in custodial files.

RFP No. 88: This request seeks documents obtained from third parties in connection with the AmerisourceBergen Investigation. The Government's response is deficient because the Government limits its production to documents produced by third parties pursuant to subpoenas. If the Government obtained documents from third parties on a voluntary basis or by any means other than a subpoena, they should be produced.

RFP No. 96: This request seeks all documents regarding the allegations in paragraphs 282 and 283 of the Complaint about Distributor 2. The Government's response is inadequate because it is limited to documents upon which the Government "relied." Defendants are entitled to all documents regarding the allegations, not just those supporting the Government's position.

* * * *

Please confirm that you are available on January 17th for a call to discuss these issues.

Very truly yours,

/s/ Joseph J. Mahady
Joseph J. Mahady

EXHIBIT B



United States Department of Justice
Consumer Protection Branch
450 Fifth Street, N.W., Suite 6400
Washington, D.C. 20001

May 17, 2024

By Email

Joseph J. Mahady, Esq.
Reed Smith LLP
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Philadelphia, Pennsylvania 19103
Jmahady@ReedSmith.com

Re: United States v. AmerisourceBergen, et al., Civ. No. 22-5209 (E.D. Pa.)

Dear Counsel:

We write to address our positions regarding (1) Defendants' requests for documents reflecting purely internal discussions among DEA employees regarding potential new statutes and regulations and the meanings of existing laws (RFP Nos. 1–14 and 67), and (2) the relevant time period for some of Defendants' requests.

First, as set forth in detail below, we agree to produce responsive non-privileged documents reflecting internal discussions about the suspicious order reporting laws if: (a) they relate to communications with external parties; (b) they relate to the facts of this case; or (c) they involve DEA employees that Defendants contend provided Defendants with advice about the suspicious order reporting laws inconsistent with the Government's legal theory. However, we do not agree to otherwise produce internal documents reflecting discussions among DEA employees regarding the meaning of the suspicious order reporting laws or potential amendments thereto, since we believe such documents would be irrelevant, as well as largely being privileged.

Second, and within the bounds set forth below, we agree to search for and produce certain documents responsive to Defendants' requests predating 2014.

I. Internal Communications Regarding Drafting and Interpretating Law

During our meet and confer of May 1, 2024, Defendants asserted that all communications from 2007 forward that involve DEA employees' discussions of the meanings of the suspicious order reporting laws or potential amendments thereto are relevant to this litigation and subject to discovery. You specifically read from an email involving a DEA attorney and high-ranking DEA policy-makers discussing the attorney's analysis of a draft regulation, and you suggested that the email and all other communications like it are plainly relevant. We expressed our disagreement, and below, we further explain our position on precisely which DEA communications regarding

Joseph J. Mahady, Esq.

May 17, 2024

Page 2 of 7

drafting and interpreting laws are subject to discovery in this litigation, and briefly summarize the supporting arguments and authorities.

As an initial matter, the Government agrees to produce the following categories of internal DEA communications:

- 1. Internal DEA communications relating to external communications.** The Government agrees to produce non-privileged documents relating to external communications between DEA personnel and outside parties regarding the suspicious order reporting laws that are responsive to Defendants' Request Nos. 1–14, 40, 67, and 74.¹ In addition to emails between DEA personnel and outside parties about the suspicious order reporting laws, such documents would also include purely internal DEA documents that reflect external communications, such as summaries of external communications prepared by DEA personnel.
- 2. Internal DEA communications concerning Defendants and the facts in this case.** The Government also agrees to produce non-privileged internal communications among DEA employees relating to the conduct at issue in this case that are responsive to Defendants' Request Nos. 1–3, 8, 10, 13, 16–24, 26, 28, 30, 37–39, 44–45, 49, 52–55, 57–62, 69–71, 88–92, and 98. This includes non-privileged communications relating to the legality of Defendants' suspicious order monitoring and reporting practices, or the application of the suspicious order reporting laws to Defendants' and their customers' conduct associated with the violations at issue.
- 3. Internal DEA communications by DEA personnel who advised Defendants regarding the meaning of the suspicious order reporting laws.** Additionally, if there are any non-attorney DEA personnel whom Defendants contend provided them with direct and specific advice (as opposed to advice shared with industry members more broadly or publicly) regarding the interpretation of the suspicious order reporting laws that Defendants contend is inconsistent with the Government's legal theory in the Complaint, the Government is willing to meet and confer to discuss adding those individuals to its list of Government custodians, the time period for which documents are available for the specific custodians, and the time period for potentially responsive

¹ All commitments to search for and produce documents included in this letter are limited to non-privileged documents identified pursuant to agreed-upon search parameters. Such commitments incorporate and do not waive the Government's objections to Defendants' Requests on grounds besides those addressed in this letter, nor do they alter the Government's previously conveyed positions regarding custodians, customer discovery, or any other matters unrelated to those addressed in this letter. References to "privileged documents" mean documents protected from disclosure by any applicable privilege, protection, or exemption, as described in General Statement No. 6 in the Government's Objections and Responses to Defendants' First Set of Requests for Production of Documents.

Joseph J. Mahady, Esq.

May 17, 2024

Page 3 of 7

documents.² If the Parties agree on the addition of such custodians and parameters for searching their records, the Government will, within the terms of the agreement, search for and produce those custodians' non-privileged internal communications regarding the interpretation of 21 C.F.R. § 1301.74 and 21 U.S.C. § 832(a).

However, we do not otherwise agree to search for or produce internal DEA documents relating to individual DEA employees' non-public commentary on the meaning of 21 C.F.R. § 1301.74 and 21 U.S.C. § 832(a), or their thoughts on potential new statutes or regulations. In addition to largely being privileged and exempt from discovery, we believe such internal legal discussions would be irrelevant to any matter legitimately at issue in the case.

1. Private, Purely Internal Communications Regarding Potential New Statutes and Regulations and the Meanings of Existing Laws Are Not Relevant

Federal Rule of Civil Procedure 26(b) provides that a party "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." In this matter, we believe the relevant questions at issue following the Court's motion to dismiss decision are: (1) whether and on how many occasions Defendants failed to report suspicious orders of controlled substances in violation of 21 U.S.C. § 832(a)(3); (2) whether such violations of 21 U.S.C. § 832(a)(3) were committed with a *mens rea* violating 21 U.S.C. § 842(a)(5); and (3) the appropriate penalties.³ The disputed internal documents have no bearing on any of these questions.

Agency employees' private thoughts about potential amendments to governing law and matters of legal analysis are irrelevant to the interpretation of § 832(a)(3). That is a legal issue for the Court alone to determine. *See, e.g., United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). Moreover, the internal legal discussions in dispute are not relevant to ascertaining Defendants'

² Defendants will need to identify any such DEA employees. As such, we are serving an interrogatory contemporaneous with this letter seeking that information and associated information about the DEA employees' alleged communications with Defendants.

³ Though we note that Defendants' Answer asserts equitable defenses that implicate other issues, we do not believe Defendants have argued that any of those defenses support their requests for the disputed DEA documents reflecting internal legal discussions, and thus we do not address them here. Additionally, it is our view that those equitable defenses cannot independently support discovery because the defenses are not legally valid. *See, e.g., United States v. California*, 332 U.S. 19, 40 (1947) (government agents "cannot by their conduct cause the Government to lose its valuable rights by their acquiescence, laches, or failure to act"); *OPM v. Richmond*, 496 U.S. 414 (1990) (estoppel is unavailable against the government in all or almost all circumstances). Though we acknowledge that no motion to strike these defenses has been filed, we understand that the Court intended for the Government to raise its arguments regarding these defenses if and when the issue became ripe in the context of a discovery dispute, and we believe it would become ripe if Defendants were to insist upon discovery relevant solely to the equitable defenses. *See* ECF No. 75 at 24:25–25:05; 30:09–30:24.

Joseph J. Mahady, Esq.

May 17, 2024

Page 4 of 7

mens rea regarding the alleged violations of 21 U.S.C. § 832(a)(3). Defendants asserted in their January 11, 2024 letter that all non-public, internal discussions among any DEA employees regarding the meanings of the suspicious order reporting laws and potential amendments thereto are relevant to judging Defendants' *mens rea* (and by extension, culpability) because such communications relate to "the reasonableness of Defendants' conduct." But that is wrong. Purely private discussions of relevant law among government employees who never communicated those opinions to Defendants could not have informed Defendants' thinking when they violated 21 U.S.C. § 832(a)(3). Moreover, the personal views of non-attorney government employees about how existing laws could be improved or might generally be interpreted are not relevant to determining whether Defendants acted negligently when they failed to report the specific suspicious orders that they discovered. Multiple courts faced with broad discovery requests for internal agency documents relating to matters of legal interpretation have denied motions to compel production and rejected the precise arguments pressed by Defendants here, finding that such documents were irrelevant to determining a defendant's *mens rea*.

For example, in *United States v. Farley*, the Seventh Circuit rejected a defendant's demand for internal agency communications about the FTC regulations the defendant allegedly violated, holding that non-public "discourse among FTC staff about the meaning of the [at issue] regulations is irrelevant" and could not inform the determination whether the defendant "should, after reading the regulations, have understood" that his actions violated the law. 11 F.3d 1385, 1391 (7th Cir. 1993). A number of district courts, including in this Circuit, have followed *Farley*'s reasoning in rejecting similar demands premised on arguments like Defendants'. See, e.g., *Consumer Fin. Prot. Bureau v. Navient Corp.*, Civ. No. 17-CV-101, 2018 WL 2088760, at *4 (M.D. Pa. May 4, 2018) (rejecting argument that internal agency discussions regarding the interpretation of a regulation "bea[r] on the reasonableness of [the defendants'] actions" and holding that "[w]hat agency staff said in communication leading up to the issuance or non-issuance of rules, policies, or guidance has no bearing"); *United States v. Wisconsin Bell, Inc.*, Civ. No. 08-C-0724, 2020 WL 13048895, at *2 (E.D. Wis. Oct. 29, 2020) ("Whether Wisconsin Bell's interpretation of the LCP rule was reasonable depends on the statutes, regulations, and the official, public statements regarding the rule. Internal and interagency communications cannot be relevant to whether Wisconsin Bell's attempts to comply with the rule were reasonable or in good faith because Wisconsin Bell did not have access to them[.]"); *S.E.C. v. BankAtlantic Bancorp, Inc.*, 285 F.R.D. 661, 668 (S.D. Fla. 2012) (denying discovery request for agency's internal policies and explaining that "SEC's internal policies and investigation decisions, in and of themselves, are not relevant to the issue of scienter. . . . Only what [defendants] knew or understood is relevant to that determination"); *United States v. Navistar Int'l Corp.*, 236 F. Supp. 3d 1049, 1057 (N.D. Ill. 2017) (internal agency communications were not relevant to determining whether defendant had "fair notice" of what the relevant law prohibited). The logic of these cases applies even more forcefully in this case, since (following the motion to dismiss decision) the Government is exclusively seeking penalties for Defendants' violations of an obligation imposed by *statute*—not by regulation.

In sum, the internal communications Defendants seek simply are not relevant to any matter at issue in this case.

Joseph J. Mahady, Esq.

May 17, 2024

Page 5 of 7

2. Defendants' Demands Improperly Target Privileged Materials

Furthermore, many of Defendants' expansive requests for documents reflecting internal legal discussions are also improper because they almost exclusively seek privileged materials. For example, Defendants' demand for all records of internal discussions "regarding any contemplated amendments, modifications, revisions, updates, or changes to 21 C.F.R. § 1301.74" (RFP No. 11) and their demand for all documents regarding "the drafting, formulation, internal approvals, and issuance of the 2020 SOR Notice" (RFP No. 12) exclusively target documents in the heartland of the deliberative process privilege, which protects from disclosure agency "documents containing 'confidential deliberations of law or policymaking, reflecting opinions, recommendations or advice.'" *Bayliss v. New Jersey State Police*, 622 Fed. App'x 182, 185 (3d Cir. 2015) (quoting *Redland Soccer Club, Inc. v. Dep't of Army of U.S.*, 55 F.3d 827, 853 (3d Cir. 1995)). These and other requests also appear to target communications protected by the attorney-client privilege, since agency attorneys are largely responsible for interpreting existing regulations and drafting new ones.

Although these privilege assertions cannot be made on a categorical basis and must be appropriately supported and logged, a party may still validly object to discovery requests aimed almost exclusively at privileged documents. *See City of Chicago v. DoorDash, Inc.*, 2023 WL 3654259, at *3 (N.D. Ill. May 25, 2023) (denying motion to compel in part due to "the privileged nature of most [responsive] communications"). This principle provides a separate and independent reason that many of Defendants' broad demands for documents relating to all DEA employees' unofficial, private views on potential new statutes and regulations and the meanings of existing laws are improper under the Federal Rules.

II. Time Periods Relevant to Defendants' Requests

As a general matter, the Government continues to believe that factual discovery in this matter should be limited to the agreed default period of January 1, 2014 through the date of the Complaint. That default period stretches back nearly five years before the first violation currently at issue in this case, and materials predating that period are generally unlikely to be sufficiently probative of Defendants' negligence or culpability to justify the burden associated with identifying and producing them.

However, we are willing to amend our responses to Defendants' Requests for Production to search for and produce certain non-privileged documents that pre-date 2014. Specifically, we agree to produce the following pre-2014 materials:

1. **DEA IMPACT Files Related to Audits or Investigations of Defendants:** The Government will collect and produce non-privileged IMPACT files associated with Defendants (based on name or DEA registration number) from roughly 2011 through the date of the Complaint. The IMPACT system was implemented in approximately 2011, though some hardcopy and electronic audit and investigative files that pre-date 2011 may have been loaded to the IMPACT system at the discretion of the inspecting or investigating DEA field office. The

Joseph J. Mahady, Esq.

May 17, 2024

Page 6 of 7

Government will consider relevant and responsive any IMPACT files that relate to Defendants' suspicious order monitoring and reporting pursuant to Defendants' Request Nos. 8 and 60–62.

2. **Defendants' DEA Registration and Renewal Files:** The Government will collect and produce non-privileged DEA registration and renewal files associated with Defendants (based on DEA registration number) and responsive to Defendants' Request No. 49, that are centrally stored by DEA's Registration and Business Operations Section, for 2007 through the date of the Complaint.
3. **Orlando Settlement Agreement Related Files:** In addition to the IMPACT files referenced above, which may include documents related to the Orlando Settlement Agreement, the Government agrees to endeavor to search the relevant field office for other non-custodial documents that may pre-date the IMPACT system that are responsive to Defendants' Request Nos. 60, 61, and 62 from 2007 through the date of the Complaint. Additionally, the Government will endeavor to identify up to two custodians who may have materials responsive to Defendants' Request Nos. 60, 61, and 62, and, if identified, to search those individuals' materials using agreed-upon search terms and produce responsive, non-privileged materials from 2007 through the date of the Complaint.

In addition to the above non-custodial and custodial sources, the Government will also search for the following pre-2014 custodial documents responsive to Defendants' requests:

1. **Existing DEA Headquarters Custodians:** For the fifteen existing DEA Headquarters custodians that the Government previously identified in its April 24, 2024 communication, the Government will extend the period for which it searches for and produces documents back to 2010.⁴
2. **Additional Custodians:** To the extent that the Government or the Defendants identify a reasonable number of additional custodians that are relevant to the 2007 to 2014 period, the Government is willing to meet and confer to discuss the addition of those custodians, the time period for which documents are available for each specific custodian, and the time period for potentially responsive documents. Any search of these custodians' materials will be subject to the agreed-upon search terms.

⁴ Not all existing DEA Headquarters custodians will have documents that cover the entire 2010 through Complaint period. For instance, some individuals' DEA employment did not cover the entire time period. However, to the extent documents are available and reasonably accessible from 2010 through the Complaint for a given custodian, the Government will search for and produce responsive, non-privileged materials consistent with the Government's existing positions regarding relevance as communicated to Defendants.

Joseph J. Mahady, Esq.

May 17, 2024

Page 7 of 7

To the extent there remain requests for which you still demand additional pre-2014 discovery, we are open to further discussion regarding those requests and would consider amending our responses if Defendants provide a convincing explanation why they are entitled to the discovery sought, as would be required of Defendants if the issue were to be brought to the Court. *See Bretter v. Peyton*, Civ. Civ. No. 22-2509, 2023 WL 3851975, at *1 (E.D. Pa. June 6, 2023) (“When a party moves to compel discovery pursuant to Fed. R. Civ. P. 37, the moving party bears the initial burden of proving the relevance of the material requested[.]”).

* * * *

Please advise whether the Government’s revised positions are acceptable to Defendants and whether Defendants believe the parties have reached an impasse on any of the matters discussed above.

Sincerely,

/s/ Michael J. Wadden

Michael J. Wadden

Trial Attorney

U.S. Department of Justice

Consumer Protection Branch

cc: Counsel of Record (by e-mail)